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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,811	01/23/2002	Clarbruno Vedruccio	U 013839-0	7403

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EXAMINER
SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
1743	

MAIL DATE	DELIVERY MODE
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/055,811	VEDRUCCIO, CLARBRUNO	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-26-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. For examination purposes, the scope of the transceiver is being treated by examiner as including, the ability to emit radio/microwave frequencies as either discrete frequencies that include the fundamental frequency and harmonics in a system that is scanned or continuously produced (see cited US 3,467,859, US 3,754,250 and Toler) or can be part of a frequency distribution produced in a pulse type of transmitter/oscillator system as in the previously applied art. Additionally from the discussion of figure 3, in the cited Lenihan (US 5,683,382) reference, it appears that an antenna matched to emit a microwave frequency (915 MHz) is capable of also emitting other harmonic and sub-harmonic frequencies. The spectrum analyzer is also being treated by examiner with a scope encompassing analyzing a set of discrete frequencies or a continuous range of frequencies.

2. Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21 has two frequencies (1350 MHz and 1800 MHz) that are greater than 1GHz and therefore outside of the normal customary definition of MHz as set forth in the March 26, 2007 response in the fourth full paragraph of page 7.

3. Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 20 it is not clear if applicant is claiming an apparatus that is only capable of producing and analyzing frequencies that are in the MHz range or that the apparatus has the capability of producing and analyzing those frequencies as a part of the total spectrum of the device. For examination purposes the claims are being treated according to the second scope since applicants' own specification fails to limit the frequency bands to the MHz range (450 MHz, 900 MHz, 1350 MHz and 1800 MHz are also 0.45 GHz, 0.9 GHz, 1.35 GHz and 1.8 GHz respectively). The 1350 and 1800 frequencies are clearly out of the MHz range since the are greater than 1 GHz. Thus, for examining purposes, a device that produces frequencies in the MHz range will be treated as anticipatory of the claimed device even though it produces frequencies outside of that range. Additionally applicant has not shown that a device can be produced that only produces and analyzes frequencies in the MHz range. See the last paragraph of page 5 and page 4, lines 19-21 relative to the disclosure of the specification being non-limiting

relative to the bands of absorption of the radiated field. Additionally, it is noted that the multiples in the paragraph beginning at page 5, line 11 of the instant specification are not limited (see "etc." at the end of the listing). Also note that column 2, lines 5-8 of the cited Lenihan reference teach that frequencies from 300 MHz to 3 GHz are considered to be microwave energy.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 4-6, 8, 14 and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Arjavalingam or Robertson (Materials Research Society Symposium Proceedings 1991).

In the paper Arjavalingam investigates anisotropic conductivity in stretch-oriented polymers with coherent microwave transient spectroscopy (COMITS). Stretch-oriented and doped polyacetylene and polyaniline are characterized using the coherent microwave transient spectroscopy technique. Conductivities parallel and perpendicular to the direction of elongation are determined. The measured orientation dependence of the sample transmissions is observed to follow the predictions of theory. Figure 1 shows a diagram of the device consisting of a transmitting and receiving antenna with the sample therebetween. The antenna radiate frequencies between 0 and 150 GHz (this inherently covers the MHz range of frequencies and the specifically claimed fundamental and harmonic frequencies of new claim 21) and general details of the process are found in the experimental section. The last sentence of page 6 refers one to other references for additional details of the experimental technique. Figure 2 shows several spectra in which the polymer has a given orientation between the electric field and the stretching direction.

In the paper Robertson discusses broadband microwave dielectric properties of polymers. Coherent microwave transient spectroscopy can be used to determine the complex dielectric properties of materials over a broad frequency range; the technique is based on radiation and detection of picosecond-duration electromagnetic transients by optoelectronically pulsed antennas. The technique is illustrated for a polyimide and a polyamide and doped polyacetylene. The apparatus is shown in figure 1 and is the same as in Arjavalingam. Figure 2 shows a

spectrum of the received signal and its Fourier transform (inset showing frequencies in the range of 0-150 GHz). Figure 5 shows several spectra in which the polymer has a given orientation between the electric field and the stretching direction.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 3, 7 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arjavalingam or Robertson as applied to claims 1-2, 4-6 and 8 above, and further in view of Bianco, Fraser, Li, Campbell or Kruger. Arjavalingam or Robertson cover the frequency range but do not investigate biological materials.

In the paper Bianco presents an improved system for microwave spectroscopy of small biological samples. A method is presented to measure the complex dielectric constant of biological liquids in the frequency range 100-2000 MHz. With such measurements, it is possible to obtain useful information about microscopic properties of living matter, with possible diagnostic applications.

In the paper Fraser uses microwave thermography to measure an index of inflamitory joint disease. Microwave thermography is a technique measuring microwave emission from sites of inflammation. Microwaves have a wavelength of around 10 cm are therefore able to penetrate clinically useful depths of up to 4 cm directly measuring tissue thermal radiation. A microwave detector was applied to the study of joint inflammation in rheumatoid arthritis and in a normal control group. Fifty-two knees were scanned using the detector and a microwave

thermographic index was calculated for each knee. A strong correlation was found between the microwave thermographic index, and the clinical and laboratory parameters measured. This technique was found to be reproducible, quick, simple to use at the bedside without a controlled environment and, since it measures internally emitted radiation, is inherently safe.

In the paper (see the English abstract) Li presents microwave radiometry in the detection of esophageal cancer. A flow diagram of microwave radiation in layered human tissues was obtained basing on the principles of bioelectromagnetics and biomedical engineering. Some important problems related to the detection of esophageal cancer by Model 846 microwave cancer detector were also studied. As a result, an appropriate method and a set of diagnostic criteria to be processed by microcomputer were obtained. Of 67 cases examined by Model 846 detector, 17 of 21 cases of esophageal cancer were positive, a true positive rate of 81%, while 36 of 46 control cases were negative, a true negative rate of 78.3%. The results indicate that this method might be of great value in the screening and early diagnosis of esophageal cancer.

In the paper Campbell discusses the dielectric properties of female human breast tissue measured *in-vitro* at 3.2 GHz. Complex permittivities of in vitro diseased and undiseased human female breast tissues have been measured at 3.2 GHz using a resonant cavity technique. Ranges of dielectric properties and water contents of these tissues are presented. Experimental data are compared with models predicted from mixture equations. Measured permittivity data lie within limits set by two-phase mixture theory, but some conductivity data are in excess of those expected for a mixture of saline and protein. At any particular microwave frequency of all tissue of a given type, the relationship between permittivity and conductivity may be parametrized using the Debye relaxation equations. For each breast tissue type a characteristic relaxation frequency was calculated and found to be lower than that of physiological saline at the same temperature. It is concluded that the dielectric relaxation of tissue water is not the only dispersive process occurring at this frequency: dielectric relaxation of bound water and the tail end of a β-dispersion may also contribute to the dielectric properties. The similarity of the dielectric properties of benign and malignant breast tumors measured in this work suggest that in vivo dielectric imaging methods will not be capable of distinguishing them.

In the paper Kruger discusses a medical imaging paradigm related to Thermoacoustic CT with radio waves. The authors evaluated images obtained with a prototypic thermoacoustic

computed tomographic (CT) scanner constructed for use at 434 MHz, a promising radio frequency for detecting breast cancer. In one excised porcine kidney, acoustic energy emanating from the kidney was detected with transducers. The resultant electric signals were used to create a three-dimensional data set. Two-dimensional images reconstructed in multiple planes were compared with state-of-the-art T1- and T2-weighted magnetic resonance images. The renal outline, parenchyma, and collecting system were clearly delineated on the thermoacoustic CT images.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure biological samples as taught by Bïanco, Fraser, Li, Campbell or Kruger at the respective wavelengths taught in the Arjavalingam or Robertson devices because of the ability to measure objects with broadband radiation as taught by Arjavalingam or Robertson and the desirability of the information available relative to clinical diagnosis at the frequencies of Bianco, Fraser, Li, Campbell and Kruger.

8. Applicant's arguments filed March 26, 2007 have been fully considered but they are not persuasive. Relative to the clarity of claims 19-21 examiner notes that 1350 and 1800 MHz are both greater than 1 GHz. Thus, based on the normal meaning of the term MHz having a frequency range of from 1 MHz to something less than 1 GHz, the specific frequencies of claim 21 do not all fit within the scope of claim 19 or 20. Thus there is a clarity issue as to what the scope of these three claims cover. Relative to the art rejections examiner notes that the apparatus claims do not specify how the spectral lines are analyzed. Furthermore claim 1 does not set any limits on the frequencies of the transceiver or the spectrum analyzer. Thus the claim is anticipated by a reference having a transceiver coupled to a spectrum analyzer regardless of the frequency range as long as the frequency range is capable of having a fundamental frequency and at least one harmonic. Since the Arjavalingam and Robertson references cover the specifically disclosed frequency range they inherently have a fundamental frequency and at least one harmonic and are anticipatory of the claimed apparatus. The preamble is not being given any weight because: first there appears to be nothing in the disclosure that would prevent one from using the instantly described device on objects other than animal tissues or living bodies and second, polymers constitute an organized chemical system. Thus the preamble is not of patentable moment.

9. The declarations under 37 CFR 1.132 filed March 26, 2007 are insufficient to overcome the rejection of the claims based upon Arjavalingam, Robertson, Bianco, Fraser, Li, Campbell and Kruger as set forth in the last Office action because: they are not of a scope commensurate with the instant claims having a set of specific frequencies and they are not analyzing anisotropy of a chemical system. It is noted that the described frequencies are within the scope claimed in claim 21 and therefore all of the problems of claims 19-21 are in this disclosed frequency range. The Balma declaration does not contain any data in support of the statements of the TRIMprob being able to detect cancer. Furthermore, the following editorial comment was made in response to a paper for which Andrea Tubaro was an author that appears to be presenting data described in that declaration.

> " Non-invasive detection of prostate cancer would for sure be a very attractive tool in the hand of the urologists, now we are appreciating the potentially increasing incidence of symptomatic disease in the growing elderly population in Europe. The technique described in this article might be such a tool, however, it does not follow the conventional tract of development. What does the probe actually measure? Following the description of biological and physical properties for the breast (in 1926), it is suggestive that such properties might also be measured in a prostate model, whether in isolated tissues, or even in animal models of 'human' size like the dog. After reading the article we remain uninformed about the influence of surrounding tissues of the pelvic floor on the detected signals. And it is this proof of the working mechanism on the isolated prostatic tissue (scientific reduction) that might convince the scientist (aren't we all?) that the detected signals are related to the condition of the prostate. For the clinical study, as the authors underline, the gold standard of diagnosis in fact should be the prostate gland removed by radical surgery in order to correlate signals to histologic size and grade of the malignant tumours."
>
> " The current evaluation of the probe is little more than looking at a black box, which many of us would like to be opened before jumping on its application. New developments always come as a surprise, but a critical assessment needs to follow these initial observations."

This appears to be an evaluation of the information presented by one of skill in the art. It appears that this person of skill in the art was not convinced by the data presented that even the described instrument was little more than a black box that was in need of further characterization before a determination of its utility could be made.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited art relates to various instruments for emitting and testing materials including tissues.

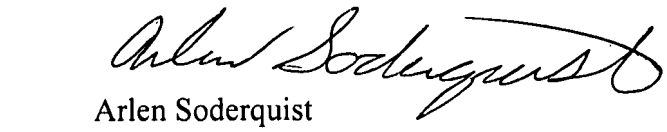
11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Arlen Soderquist
Primary Examiner
Art Unit 1743